JUL 31 2000

K001690

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS for PROTECTIV* Safety Blood Collection Needle

Johnson & Johnson Medical
2500 Arbrook Boulevard
P.O. Box 90130
Arlington, Texas 76004-3130

Date: May 26, 2000

1. REGULATORY AUTHORITY

Safe Medical Devices Act of 1990: 21 CFR 807.92

2. CONTACT PERSON

Dorene Markwiese
Project Manager, Regulatory Affairs
817-262-4450

3. NAME OF MEDICAL DEVICE

Classification Name: Blood Specimen Collection Device
Common/Usual Name: Blood Specimen Collection Device
Proprietary Name: PROTECTIV* Safety Blood Collection Needle

4. DEVICE CLASSIFICATION

The Clinical Chemistry panel has classified Blood Specimen Collection Device (21CFR 862.1675) into Class II, Special Controls under section 513 of the Act.

5. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The PROTECTIV* Safety Blood Collection Needle is substantially equivalent to the BECTON DICKINSON VACUTAINER Brand eclipse Blood Collection Needle(K982541) and BECTON DICKINSON VACUTAINER Safety Blood Collection Assembly, Pre-attached SafetyGlide Needle and Direct Draw Adapter(K972404).

6. INTENDED USE

PROTECTIV* Safety Blood Collection Needle and holder is intended for use in the collection of venous blood using evacuated blood collection tube. PROTECTIV* Safety Blood Collection Needle is intended to be marketed as a sterile, single or multi-sample, single use device.

PROTECTIV* Safety Blood Collection Needle may be used in any appropriate patient populations.

7. DESCRIPTION OF DEVICE

The PROTECTIV* Safety Blood Collection Needle is a sterile, , one-piece blood collection needle and holder assembly, single use medical device with multi-link safety mechanism. The product is designed for blood sample collection into separately supplied blood collection tubes. The size of this device is analogous to conventional blood collection holders with an attached blood collection needle. The integrally molded safety mechanism is manually activated after the needle is removed from the patient's vein.

8. SUMMARY OF MATERIAL TESTING

The PROTECTIV* Safety Blood Collection Needle meets ISO 10993-1 requirements for material safety and biocompatibility.

9. SUMMARY OF SIMULATED USE STUDY

There were a total of 500 PROTECTIV* Safety Blood Collection Needles successfully inserted and evaluated. No sharps injuries or failures of the protective feature occurred.

The results of this study support the claim that the PROTECTIV* Safety Blood Collection Needle can reduce the risk of accidental needlestick injuries. The positive responses from the participants regarding insertion and use characteristics demonstrate the PROTECTIV* Safety Blood Collection Needle is easy to use, requires little or no change in usual technique and meets customer requirements.

10. CONCLUSION

The material testing simulated use data demonstrate that the PROTECTIV* Safety Blood Collection Needle is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2000

Mr. Donald D. Solomon
Vice President, R&D
Johnson & Johnson Medical
2500 Arbrook Boulevard
P.O. Box 90130
Arlington, Texas 76004-3130

Re: K001690
Trade Name: Protective Safety Blood Collection Needle
Regulatory Class: II
Product Code: FMI
Dated: May 26, 2000
Received: June 2, 2000

Dear Mr. Solomon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Devices Evaluation
Center for Devices and
Radiological Health

Enclosure

Johnson & Johnson
MEDICAL™

ATTACHMENT 1
Indications for Use

510(k) Number: _____

Device Name: **PROTECTIV* Safety Blood Collection Needle**

Indications for Use:

PROTECTIV* Safety Blood Collection Needle and holder is intended for use in the collection of venous blood using evacuated blood collection tubes. The integrally molded safety mechanism, which is manually activated after sample collection, reduces the risk of accidental needle sticks.
PROTECTIV* Safety Blood Collection Needle is intended to be marketed as a sterile, single or multi-sample, single use device.
PROTECTIV* Safety Blood Collection Needle may be used in any appropriate patient populations.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucanic

(Division Sign-Off)
Division of **Dental, Infection** Control,
and General **Hospital** Devices
(ODE) Number K001690

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